REMARKS

1. Claim 11 has been amended to make it absolutely clear how to parse the body, i.e., the composition comprises both

(a) α-MSH and/or α-MSH equivalent, and

(b) EPO and/or an EPO equivalent.

We believe that this was already adequately conveyed by (1) the term "combination" and (2) the distinction between "and" and "and/or", but as claim 11 is the main claim, we did not want there to be any room for doubt on this point.

2. Method of use claim 1 has been amended to depend from claim 11. Hence, claims 1, 2, 4, 5 and 13-17 are directly or indirectly dependent on claim 11, and should be rejoined pursuant to MPEP 821.04 if claim 11 is deemed allowable. See pages 5-6 of the restriction mailed August 11, 2004.

3. We disagree with the rejection of claim 11 by the examiner. The examiner states that Claim 11 (a pharmaceutical composition comprising a combination of α-MSH or and/or α-MSH equivalent and EPO and/or an EPO equivalent together with a pharmaceutically acceptable carrier) is unpatentable over Shohaib et al. in view of Kwon et al. The examiner argues that Shohaib et al. describes the use of EPO and Kwon et al. the use of α-MSH for the same purpose and thus that it is prima facie obvious to combine the two compositions in a third composition.

According to the examiner, the references demonstrate the use of EPO and α-MSH, respectively, for the treatment in renal failure patients. Thus, the examiner argues that it would be obvious to one skilled in the art to combine the two compounds.

We do not agree that the two references describe the use of EPO and α-MSH, respectively, for the same purpose. In support of our position, we submit the enclosed declaration of Dr. Thomas Jonassen. As explained by Dr. Jonassen, Shohaib et al. do not describe treatment of renal failure. Instead, Shohaib et al.

describe the use of EPO in the treatment of **anaemia** in a post-renal transplant patient. The anaemia is **not** due to renal failure. The reference mentions a woman who has chronic renal failure and receives a renal transplant.

After the renal transplantation her serum creatinine clearance is measured several times and is 50 ml/min and 60 ml/min, respectively (p. 82, column 1, 2nd paragraph, line 8, 22-23, 33). According to Dr. Jonassen, a creatinine level of 50 ml/min or 60 ml/min is considered indicative for normal function of a transplanted kidney and the woman is therefore **not** suffering from chronic renal failure. This is further supported by the author's comment on her graft function of the transplanted kidney p. 82, column 2, 2nd paragraph, lines 2-4: "her graft function was satisfactory and could not account for her anaemia". Thus, Shohaib et al. teach the use of EPO in the treatment of **anaemia** and not renal failure.

Likewise according to the Jonassen declaration, Kwon et al. teach that α-MSH treatment reduces downregulation of renal aquaporins and reduces poyuria in rats with ischemia-induced acute renal failure. In more details, Kwon et al. examine the effect of temporary renal ischemia and reperfusion on the expression of renal aquaporins and urinary concentration in rats with bilateral ischemia-induced acute renal failure.

Subsequently, they test whether reducing ischemia/reperfusion injury by treatment with α-MSH affects the expression of aquaporins and urine output (page F413, column 1, lines 10-12). They find that α-MSH treatment reduces the expression of aquaporins and also reduces urine output (page F413, column 1, lines 34-36).

Thus, Kwon et al. teach that α-MSH treatment of rats with acute renal failure results in a reduced ischemia-induced **downregulation of renal aquaporins** and in **a reduced polyuria.**

Dr. Jonassen states that this is not the same as teaching the use of α-MSH for the treatment of anaemia. Importantly, anaemia is not observed in acute renal failure.

In conclusion, Shohaib et al. and Kwon et al. do not teach the use of EPO and α-MSH, respectively, for the same purpose and thus, it is not obvious to combine EPO and α-MSH in a composition.

Respectfully submitted,

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Enclosure
-Declaration of Thomas Jonassen

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